K002829

MAR 2 6 2001

510(k) Summary

Submission

Submitted by:	dj Orthopedics, LLC 2985 Scott Street Vista, CA 92083-8339 (760) 727-1280 Phone, (760) 734-5608 Fax
Application Preparor: *(contact for additional information)*	Alaron Technologies, LLC Jamal Rushdy 990 Park Center Drive, Suite H Vista, CA 92083 (760) 599-1674 Phone, (760) 599-1675 Fax
Date of preparation:	September 8, 2000

Device

Common Name:	Anchor
Trade Name:	dj Orthopedics Femoral Anchor
Classification Name:	Single/multiple component bone fixation appliances and accessories
Predicate Device:	Innovasive Devices 8mm and 10mm LinX HT Ligament Fastener (K980334 and K970316). Mitek Ligament Anchor (K926270).

Description and Intended Use

The dj Orthopedics' Femoral Anchor is a barbed anchor type device to facilitate soft tissue fixation such as a tendon or ligament within the femoral bone. The dj Orthopedics Femoral Anchor is an "A" shaped device consisting of outer barbs to facilitate fixation and a proximal keyhole through which to thread the tendon or ligament grafts.

The implant is designed in four sizing configurations: 8mm, 9mm, 10mm, and 11mm. These nominal implant sizes refer to the size of the femoral tunnel preparation, and accommodate various tendon graft sizes. The nominal implant length is 30mm.

The Femoral Anchor is intended for use in bone fixation of ligament and tendon grafts during cruciate ligament reconstruction surgeries. This is the same indication as the predicate devices.

Technological Characteristics

The implant is designed to be compressed and placed on an insertion tool. A tendon or ligament graft is passed through the keyhole and the ends are secured to the insertion tool. Once the implant is introduced into a prepared femoral tunnel and released past the cortical wall, the barbed legs engage the cancellous bone to facilitate fixation.

The predicate devices are anchor device designed to facilitate soft tissue fixation. The predicate devices also utilize an eyelet through which to thread the tendon or ligament grafts. The Innovasive predicate device utilizes threads on the outer sleeve to engage cancellous bone. The dj Orthopedics and predicate devices are both designed for insertion into a prepared femoral tunnel, utilizing a keyhole though which to thread the tendon or ligament graft.

Pull-out testing of the dj Orthopedics Femoral Anchor shows the performance characteristics are substantially equivalent to previously published performance characteristics of similar fixation methods.

Conclusion

The predicate devices and the dj Orthopedics Femoral Anchor are both anchor type devices used to facilitate soft tissue fixation such as a tendon or ligament within the femoral bone. Both devices utilize an eyelet geometry through which to thread the tissue graft. The dj Orthopedics Femoral Anchor is offered in sizes that are comparable to the size range of predicate device. The intended uses are the same.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2001

DJ Orthopedics, LLC
c/o Mr. Jamal D. Rushdy
Alaron Technologies, LLC
990 Park Center Drive, Suite H
Vista, California 92083

Re: K002829
Trade Name: DJ Orthopedics Femoral Anchor
Regulatory Class: II
Product Code: MBI
Dated: December 15, 2000
Received: December 26, 2000

Dear Mr. Rushdy:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

Ver/ 3 - 4/24/96

Applicant: dj Orthopedics, LLC

510(k) Number (if known): K002829

Device Name: dj Orthopedics Femoral Anchor

Indications For Use:

The dj Orthopedics Femoral Anchor is intended for use in the fixation of ligament and tendon grafts in cruciate ligament reconstruction surgeries.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Milhous

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K002829

(Per 21 CFR 801.109)

(Optional Format 1-2-96)